

K953522

XII. SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: July xx, 1995

Device Name: Ryder Balloon Catheter Inflation Syringe

Classification Name: Balloon Catheter Inflation Syringe

Manufacturer: Ryder International Corporation, 100 Curt Francis Road,
Arab, AL 35016

Contact: Mr. D. Clark, Ryder International Corporation, 100 Curt Francis
Road, Arab. AL 35016

Predicate: Merit Medical Systems Monarch™ Balloon Catheter Inflation
Syringe

**Device Description/
Intended Use:**

The Ryder Balloon Catheter Inflation Device consists of a plastic syringe with a screw-type plunger and a locking lever and rotating palm grip that control the plunger, a manometer to measure pressure and a high pressure connecting tube.

The Ryder Device has a fluid capacity of 20 cc. and an operating pressure range of vacuum to 30 bars.

The Ryder device is intended for single use inflating of a balloon catheter, monitoring the pressure within the catheter and deflating the balloon catheter during angioplasty procedures.

Summary of Safety Testing:

The materials of the device which contact the contrast solution in use have been tested using USP guidelines and the results of these studies indicate that the product is safe for its intended use.